



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

February 27, 2015

OLYMPUS MEDICAL SYSTEMS CORP.

% Sheri L. Musgnung

Manager, Regulatory Affairs

Olympus Corporation of the Americas

3500 Corporate Parkway, P.O. Box 610

Center Valley, PA 18034-0610

Re: K143303

Trade/Device Name: Single Use Biliary Balloon Dilator

Regulation Number: 21 CFR§ 876.5010

Regulation Name: Biliary catheter and accessories

Regulatory Class: II

Product Code: FGE

Dated: February 12, 2015

Received: February 13, 2015

Dear Sheri L. Musgnung,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

  
Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K143303

Device Name

Single Use Biliary Balloon Dilator

Indications for Use (Describe)

Single use balloon dilator to be used in conjunction with Olympus endoscopes for dilating strictures of the biliary tree and the major duodenal papilla during endoscopic applications.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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**510(k) SUMMARY**  
**Single Use Biliary Balloon Dilation**

February 27, 2015

**5.1 General Information**

- Applicant: OLYMPUS MEDICAL SYSTEMS CORP.  
2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan  
192-8507  
Establishment Registration No: 8010047
- Official Correspondent: Sheri L. Musgnung  
Manager, Regulatory Affairs  
Olympus Corporation of the Americas  
3500 Corporate Parkway PO Box 610  
Center Valley, PA 18034-0610, USA  
Phone: 484-896-3147  
FAX: 484-896-7128  
Email: sheri.musgnung@olympus.com
- Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.  
34-3 Hirai, Hinode-machi,  
Tokyo, Japan 190-0182  
Establishment Registration No.: 3003637092

**5.2 Device Identification**

- Device Trade Name: Single Use Biliary Balloon Dilator
- Common Name: Balloon Dilation Catheter
- Regulation Number: 876.5010
- Regulation Name: Biliary catheter and accessories
- Regulatory Class: II
- Classification Panel: Gastroenterology and urology
- Product Code: FGE

### 5.3 Predicate Device Information

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■ Device Name:	Single use balloon dilator MaxPass™
■ Common Name:	Balloon Dilation Catheter
■ Applicant	Olympus Winter & Ibe, GmbH
■ 510(k) No.	K050502

### 5.4 Device Description

The subject device is a single use biliary balloon dilator to be used in conjunction with Olympus endoscopes for dilating strictures of biliary tree and the major duodenal papilla during endoscopic applications.

The subject device is a triple lumen catheter with a balloon mounted to the distal end of the catheter. Balloon dilators are used to exert radial force to dilate narrow duct segments. The balloon at the distal end of the subject device is inserted to the stricture of biliary tree or the major duodenal papilla. And the balloon is inflated by injection of inflation fluid from the balloon lumen hub. The stricture of biliary tree or the major duodenal papilla is dilated by the inflated balloon.

### 5.5 Indications for Use

Single use balloon dilator to be used in conjunction with Olympus endoscopes for dilating strictures of the biliary tree and the major duodenal papilla during endoscopic applications.

### 5.6 Comparison of Technological Characteristics

Compared to the predicate device, the proposed subject device; Single Use Biliary Balloon Dilator, has similar technological characteristics. There is no significant difference that affects the safety or effectiveness of the subject device.

## **5.7 Summary of non-clinical testing**

The following performance testing was conducted to demonstrate the basic performance of the subject device and confirmed that the subject device performs as intended.

- Insertion/withdrawal forces from endoscope
- Advance/retreat forces of the guidewire
- Balloon diameter
- Balloon deflation time
- Balloon formation after deflation
- Tensile testing
- Balloon and tube shaft burst pressure
- Packaging validation
- Shelf life testing

· Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verification tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

· Biocompatibility testing is performed in accordance with the FDA Guidance, "Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices, Blue Book Memo, G95-1".

The following standards have been applied to the Single Use Biliary Balloon Dilator.

- ISO 10993-1
- ISO 10993-5
- ISO 10993-10
- ISO 11135
- ISO 14971
- ASTM F-1980-07

## **5.8 Conclusion**

When compared to the predicate device, the Single Use Biliary Balloon Dilator does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device.